REMARKS

I. Claim Amendments

Claims 2-5 are currently pending in the application, claim 1 having been previously cancelled. Following entry of the present amendment, claim 2 is currently amended, claims 3-5 are cancelled and new claims 6 and 7 are added. It is believed that no new matter has been added.

Claim 2 has been amended to remove the recitation to sheep and to limit the method to dogs and cats. Claim 2 has also been amended to indicate that the dogs and cats receive a properly nutritious diet. Support for this amendment may be found throughout the specification which states, "[w]e have now found a range of dietary selenium that stimulates hair growth of dogs and cats *receiving a properly nutritious diet.*" Specification at page 1, paragraph 2, emphasis added. In addition, the specification also indicates that the diet provides "nutritional sustenance." Specification at page 2, line 8. Claim 2 has also been amended to indicate that the animals are in need of treatment, support for which amendment may be found throughout the specification, e.g., at page 3, paragraph 8. Claim 2 has also been amended to include 0.1 as the lower limit of the range of selenium reported to increase hair growth rate and support for this amendment may be found through out the specification, for example, at page 1, lines 33-35, page 2, lines 2-3, page 2 lines 24-26 and page 4, lines 21-23.

Support for new claim 6 may be found at page 2, lines 30-35. Support for new claim 7 may be found at page 1, lines 27-30 and page 3, lines 6-10. Upon entry of these amendments, claims 2, 6 and 7 will be pending in the application, reconsideration of which is respectfully requested.

II. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 3-5 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not provide enablement for "at least assisting in preventing" poor hair growth or alopecia in animals as claimed. In response, Applicants have cancelled these claims thus mooting this rejection, and Applicants respectfully request that it be withdrawn.

III. Rejection Under 35 U.S.C. §102

Claims 2-4 are rejected under 35 U.S.C. §102(b) as being anticipated by NAC, Nutrient

Requirements of Sheep (6th Revised Ed. 1985) (hereinafter "NAC-NRS"). In response, Applicants have removed reference to sheep in claim 2 and have cancelled claims 3 and 4.

Claims 2-5 are rejected under 35 U.S.C. §102(b) as being anticipated by Van Vleet (JAVA (1975) 1975 Vol. 166, No. 8 pp 769-774). Applicants have cancelled claims 3-5, thus mooting this rejection with regard to these claims.

With regard to the rejection of claim 2 which remains pending, the Examiner asserts that Van Vleet discloses supplementing the diet of dogs deficient in vitamin E and selenium with 0.5 ppm Se and 1.0 ppm Se as sodium selenite. According to the Examiner, this reference inherently reads on the claimed method as the amounts administered to dogs fall within the claimed range of selenium of claim 2.

According to the Federal Circuit, "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (internal citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). See also MPEP 2112.

In this case, Applicants respectfully submit that there is insufficient data in Van Vleet to support a rejection of claim 2 based on inherency. The basal diet described in Van Vleet was not only selenium deficient *but it was also Vitamin E deficient.* Specifically, the supplemented diets contained either 30 IU alpha-tocopherol/kg (diet 2), 0.5 ppm selenite (diet 3) or 1.0 ppm selenite (diet 4) (see Table 1, page 770). None of the diets contained sufficient dietary amounts of both selenium and Vitamin E. As such, it is unclear whether an increase in hair growth rate would *necessarily* occur in the animals in the study described in Van Vleet as these animals were not fed a nutritionally balanced diet such as described in the instant application. Thus, Applicants respectfully submit that claim 2 is not inherently anticipated by Van Vleet and that the rejection under 35 U.S.C. §102(b) is improper and should be withdrawn. In an effort to advance prosecution, however, Applicants have amended claim 2 to clarify that the claim is directed to

dogs (and cats) in need of treatment.

IV. Rejection Under 35 U.S.C. §103

Claims 2-4 are rejected under 35 U.S.C. §103(a) as being unpatentable over NAC-NRS. As discussed above, the Applicants have cancelled claims 3 and 4 and limited claim 2 of the present invention to dogs and cats thus mooting this rejection.

Claims 2-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over NAC, Nutritional Requirements of Cats (1986, hereinafter "NAC-NRC") in view of Dey et al. (Current Science (1999) Vol. 77, No. 2 pp276-280). According to the Examiner, NAC-NRC teaches that a minimum level of 100 micrograms Se/kg diet is recommended in cats and that an excess of 5 mg/kg is toxic for other animals but does not appear toxic to cats. Dey et al. is said to describe the toxic effects of selenium on the hair of animals such as flying squirrel, leopard cat, civit cat and leopard. According to the Examiner, this combination of references suggests the treatment of poor hair growth or alopecia in cats by disclosing the recommended minimum requirement of 100 micrograms Se/kg diet and that an excess of 5 mg/kg is toxic, such toxicity being demonstrated in certain animals as resulting in brittle hair and loss of long hair.

In order to establish a prima facie case of obviousness, three basic criteria must be met. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. There also must be a reasonable expectation of success and, finally, the prior art reference (or combined prior art references as the case may be) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not in the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2143.

In this case, the Examiner has argued that, given the combination of NAC and Dey et al.,

> [I]t would have been well within the skill of and one of ordinary skill in the art to restrict the amount of selenium in the diet to less than 5 mg/kg of diet to a minimum of 100 micrograms/kg of diet with the expectation that said amount would meet the selenium nutritional requirements of the cat while treating or reducing the risk of poor hair growth or alopecia due to selenium toxicity. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention

> was made, because every element of the invention has been taught by the teachings of the cited reference.

Office Action of November 21, 2006 at page 11.

Applicants respectfully submit that as amended herein, claim 2 is clearly directed to a method for *controlling the rate of hair growth* in a dog or cat receiving a *properly nutritious diet*; a nutritionally complete and balanced cat or dog diet being familiar to one of skill in the art. The claims of the instant invention are not directed to treating or reducing the risk of poor hair growth or alopecia *due to selenium toxicity*. Indeed, Dey et al. describes a study of heavy metal toxicity and trace-element deficiency in wild animals in India and mentions that brittle hair and loss of long hair are known toxic effects of selenium. NAC-NRC suggests a minimum level of selenium that is desirable in cats, but does not provide a level of selenium that is toxic to cats. There is nothing in Dey et al. or NAC-NRC, either alone or combined, that teaches or suggests that cats fed a properly nutritious diet including an amount of selenium as claimed in the instant invention would exhibit a change in the *rate* of hair growth. Indeed, loss of hair or brittle hair in a cat due to selenium toxicity might be avoided by feeding the amount of selenium recommended in NAC-NRC (although it is unclear what a toxic amount would be to a cat), but the Applicants respectfully submit these references certainly do not teach or suggest that an increase in hair growth rate might be achieved as claimed with a reasonable expectation of success. As such, Applicants submit that rejection of the claims under 35 U.S.C. §103(a) is inappropriate and reconsideration and withdrawal of this rejection is respectfully requested.

Claims 2-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Arthur et al. (Biological Trace Element Research 1992 33:37-42) in view of Awadeh et al. (J. Anim. Sci. 1998 78:1204-1215), Ahsan et al. (J. Med. Investigations 1998 44:179-184), Messenger (Br J. Dermatol. 2000 142(4):633-634), Daminet et al. (Can. Vet J 2000 Vol. 41:699-703), NAC-NRS, NAC, Nutrient Requirements of Dogs (1985) (hereinafter "NAC-NRD") and NAC-NRC. According to the Examiner:

> Arthur et al. discloses that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases that convert thyroxine to triodothyronine (T3);
>
> Awdeh et al. discloses that Se supplementation increases T3 levels in cows, guinea pigs

and calves and that Se deficient rats have reduced T3 plasma levels;

Ahsan et al. discloses that T3 regulates growth, differentation and development of various tissues and that hypothyroidism leads to dry, coarse and brittle hairs that become increasingly thinner and that spare scalp hair, loss of the outer third of the eyebrows and diminished body hair are often seen in hypothyroidism, and that T3 stimulates the proliferation and/or metabolism of outer root sheath cells and dermal papilla cells;

Messenger discloses thyroxine, converted to the hormone triodothyronine, increases hair length in rats and hair growth in sheep and badgers;

Daminet et al. discloses that alopecia is a common clinical sign of hypothyroidism;

NAC-NRS discloses feeding a minimum of 0.1-0.2 mg/kg Se diet dry matter to sheep, a maximum amount of 2 ppm and that prolonged levels of 3 ppm are toxic, with loss of wool a sign of such toxicity;

NAC-NRD discloses that dogs fed a purified, Torula yeast-based diet deficient in Se over a period of 40-60 days exhibited signs of deficiency whereas dogs supplemented with 0.5 mg and 1.0 mg/kg Se did not. Also, that the minimum concentration of Se in dog food formulated for growth is 0.11 mg/kg dry basis and the minimum Se requirement of dogs for growth and maintenance (amounts per kg of body weight per day is 6.0 and 2.2 micrograms in growing beagle puppies and adult dogs, respectively; and

NAC-NRC discloses that a Se deficiency in cats has not been observed but a specific dietary requirement likely exists. It discloses that a minimum level of 100 micrograms Se/kg diet is recommended in cats and that an excess of 5 mg/kg is toxic for other animals but does not appear toxic to cats.

According to the Examiner, the prior art does not expressly disclose a method for controlling the rate of hair growth or treating poor hair growth or alopecia in a dog or cat with about 0.5 to about 4.5 Se mg/kg. The Examiner is of the opinion, however, that the prior art suggests such as thing given the

disclosure that selenium deficiency impairs thyroid hormone metabolism and conversion to T3, that selenium deficiency results in T3 deficiency, that T3 stimulates hair cell growth and/or metabolism, that administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in rats, sheep and badgers, and that alopecia is a symptom of hypothyroidism. The Examiner also states that the prior art also discloses the selenium requirements for dogs, cats and sheep which amounts fall within or overlap the claimed range of about 0.5-4.5 mg/kg diet dry matter. Thus, according to the Examiner, it would have been well within the skill of one of ordinary skill in the art and one would have been motivated to administer similar amounts of Se to dogs or cats with the expectation that Se administration would control the rate of hair growth or treat poor hair growth or alopecia in animals in which poor hair growth or alopecia is due to hypothyroidism that is caused by Se deficiency and treatable by Se supplementation and to use levels of Se below 5 mg/kg diet dry matter in order to reduce the risk of selenium toxicity.

In response to the rejection, Applicants have cancelled claims 3-5 and amended claim 2 to make it clear that the claims are directed to animals that are fed a properly nutritious diet and thus are not selenium deficient, and thus do not suffer from hair growth problems due to hypothyroidism due to an insufficiency in this element. Applicants note that in response to Applicant's earlier argument that the animals are not selenium deficient, the Examiner referred to Example 1, pointing out that the beagles tested were fed a basal diet that was deficient in selenium. Applicants respectfully point out that the animals in the study described in Example 1 were initially *pretreated* with a selenium deficient basal diet for 3 weeks and such depletion/repletion *prior* to actual administration of a test diet is common in animal feeding studies. In fact, the animals were *not* selenium deficient during the actual 24 weeks of experimentation and at the times hair growth rate was assayed (unless the dog received an experimental diet of this type by design to serve as a control; see e.g., page 3, paragraphs 11 and 12). Thus, Applicants respectfully submit that as the increased rate of hair growth seen in Example 1 was not determined in selenium deficient animals, nor are the claims directed to methods of controlling the rate of hair growth in selenium animals, the rejection of the claims under 35 U.S.C. §103 is improper and should be withdrawn.

The Examiner has indicated in his rejection that "the Applicant argues that dogs fed diets containing amounts of selenium inside the claimed range had higher rates of hair growth than dogs fed diets containing amounts of Se outside of the claimed range. This is not accurate as beagles fed 0.123 mg of Se/kg diet has similar rates of hair growth as beagles fed 0.527 mg/kg and 1.025 mg/kg (Specification,

Paragraph 0015, Table 1)." Office Action, page 16, lines 13-17. In response, Applicants thank the Examiner for noting this discrepancy and have amended the claimed range to include this lower concentration, support for which may be found throughout the specification.

The Examiner has also pointed out that none of the amounts tested exhibited a rate of hair growth that was at least the same as that reported to be the average rate of hair growth for beagles and, as such, the example fails to support the criticality of the claimed range for poor hair growth Specifically, the Examiner points to Yu et al. (Journal of Animal Physiology and Animal Nutrition 2006 90: 146-151) which discloses that a daily hair growth rate for beagle dogs is 0.34-0.40 mm which is higher than any of the daily hair growth rate data set forth in Table 1 of the Specification (0.23 mm). The authors in Yu et al. (i.e, the Applicants) acknowledge this difference in the publication, stating "[t]he reason for the discrepancy is not clear. Differences in age and the skin regions where hair growth was measured may contribute to the discrepancy as majority of the dogs used in the present study were more than 7 years old." Yu et al. page 150. In addition to a possible difference in experimental conditions under which the hair growth was measured, Applicants respectfully submit that, within the study as presented as Example 1, there was a measurable increase in hair growth rate compared to the other concentrations within the study. The fact that the average hair growth rate in beagle dogs as reported in Example 1 is different than a previously reported value does not change the fact that an increase in growth rate was observed in the controlled study described in the Specification. Indeed, the conditions under which the previously reported average growth rate was determined are not even described in this reference, so it is difficult to compare this value with the value disclosed in Example 1 and draw any meaningful conclusions from the comparison. As such, the Applicants respectfully submit that the example does support the criticality of the claimed range as amended herein.

Based on the arguments presented above, Applicants submit that the claimed invention is not prima facie obvious under 35 USC 103(a), and Applicants respectfully request that this rejection be withdrawn.

V. Conclusion

In summary, the claims have been amended and new claims added such that the Applicants believe that the Examiner's rejections under 35 U.S.C. §§ 112, 102 and 103 have been obviated or overcome. Reconsideration of the Application as amended herein and allowance of the pending claims

are respectfully requested.

If the Examiner believes that a telephonic interview would advance prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided below.

Respectfully submitted,

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